7. REGULATIONS AND ADVISORIES

The international, national, and state regulations and guidelines pertaining to arsenic and its metabolites in air, water, and other media are summarized in Table 7-1.

ATSDR has derived a chronic oral MRL of 0.0003 mg/kg/day for inorganic arsenic based on a NOAEL for dermal effects in humans (Tseng 1977; Tseng et al. 1968) and a provisional acute oral MRL of 0.005 mg/kg/day for inorganic arsenic based on gastrointestinal effects and facial edema in humans (Mizuta et al. 1956).

EPA's Integrated Risk Information System (IRIS) lists an oral reference dose (RfD) of 0.0003 mg/kg/day for arsenic (IRIS 1999). No reference concentration (RfC) for chronic inhalation exposures to arsenic was reported.

The Department of Health and Human Services (DHHS) has determined that inorganic arsenic is a known carcinogen. The EPA has determined that inorganic arsenic is a human carcinogen and has assigned it the cancer classification, Group A (IRIS 1999). EPA's quantitative estimates of carcinogenic risk from oral exposures include a cancer slope factor of 1.5 mg/kg/day and a drinking water unit risk of 0.00005 µg/L. The inhalation unit risk for cancer is 0.0043 µg/m3) (IRIS 1999). The International Agency for Research on Cancer (IARC) cites sufficient evidence of a relationship between exposure to arsenic and human cancer. The IARC classification of arsenic is Group 1 (IARC 1987). The American Conference of Governmental Industrial Hygienists (ACGIH) classifies arsenic (elemental and inorganic compound) as a confirmed human carcinogen; cancer category A1 (ACGIH 1998).

Several arsenic compounds have been designated as "extremely hazardous substances" or "hazardous substances" pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980 (EPA 1995b, 1996c). The owner or operator of any facility that produces, uses, or stores any extremely hazardous substance or CERCLA hazardous substance in an amount exceeding the "threshold planning quantity" is required to immediately report any release to any environmental media, if the amount released is equal to or exceeds the specified "reportable quantity" assigned to the substance. As extremely hazardous substances, when arsenic compounds are formulated as solids, they are subject to either of two threshold planning quantities (EPA 1996c). If the solid exists in powdered form and has a particle size less than 100 microns, it is subject to the lower number. If the solid does not meet this criteria, it is subject to the higher number. Under this rule, the threshold planning quantity for arsenous

pentoxide and arsenous oxide is the same at 10 and 10,000 pounds (4.54 and 4,540 kg) (EPA 1996c). The threshold planning quantity for arsenous trichloride is 500 pounds (270 kg). The reportable quantity for each of these three compounds is 1 pound (0.454 kg) (EPA 1995b). Approximately 11 arsenic compounds are designated as "hazardous substances" under Sections 101(14) and 102(a) of CERCLA and must meet the requirements for reporting releases to the environment in accordance with 40 CFR 302.4. The statutory sources for this designation include Sections 307(a) and 311(b)(4) of the Clean Water Act (CWA), Section 3001 of the Resource Conservation and Recovery Act (RCRA), and Section 112 of the Clean Air Act (CAA) (EPA 1995b). The reportable quantities for these compounds are given in Table 7-1 (EPA 1995b).

The statutory requirements of the CAA also contain a mandate for EPA to evaluate and control emissions of hazardous air pollutants (HAPs). Section 112(b)(1) of the Act includes a list of substances that have been designated as HAPs. The mandate requires EPA to identify specific categories of sources (new and existing) that emit or have the potential to emit these substances to the environment and to promulgate emissions standards for each source. Inorganic arsenic compounds have been identified and listed as HAPs (U.S. Congress 1990). The source categories to which emission standards for arsenic apply include primary copper smelters (EPA 1986g, 1998e), arsenic trioxide and metallic arsenic production facilities (EPA 1986a), glass manufacturing plants (EPA 1990g), primary lead smelters (EPA 1998d), and the Portland cement manufacturing industry (EPA 1998c). Arsenic also appears on the list of toxic chemicals subject to Section 313 of the "Emergency Planning and Community Right-to-Know-Act of 1986" (EPA 1995a).

The discharge of arsenic in the waste waters from point sources is regulated by the Effluent Guidelines and Standards provided in Subchapter N of Title 40 of the Code of Federal Regulations (40 CFR). The statutory authority for these regulations is the CWA. Pursuant to the Act, these regulations prescribe effluent limitations guidelines for existing sources, standards of performance for new sources, and pretreatment standards for new and existing sources (EPA 1981b). The point source categories for which arsenic and arsenic compounds are regulated include inorganic chemical manufacturing (EPA 1982a), nonferrous metals manufacturing (EPA 1990a), timber products processing (EPA 1981b), and electrical and electronic components manufacturing (EPA 1983a). On February 6, 1998, the EPA published a proposed rule which represented the Agency's first effort to develop CWA national effluent limitations guidelines and standards for waste water discharges from commercially-operated hazardous waste combustor facilities that are regulated as "incinerator" or "boilers and industrial furnaces" under RCRA. These facilities would make up a defined subcategory of the waste combustors point source category

(EPA 1998b). Arsenic is also regulated as a waste water pollutant in discharges from new and existing facilities that manufacture metallo-organic active ingredients (EPA 1996a). The limitation for the discharge of pollutants to navigable waters is zero (EPA 1996a).

Under the authority of RCRA, arsenic and arsenic compounds are regulated as the hazardous constituent(s) in several listed hazardous wastes (EPA 1997d). On May 26, 1998, the EPA published in the *Federal Register* a final rule which promulgated "Land Disposal Restrictions" treatment standards for metal-bearing wastes, including wastes found to be hazardous because they exhibit the toxicity characteristic, and hazardous wastes from mineral processing (EPA 1998f). The promulgated standards known as the "universal treatment standards" (UTS) are based on technologies that have been demonstrated to be effective in reducing contaminant levels in metal-bearing wastes or similar wastes (EPA 1998f). For waste waters identified by the hazardous waste code DOO4, the promulgation established a UTS of 1.4 mg/L for arsenic (EPA 1998f).

In order to protect the groundwater within the boundaries of facilities that treat, store, or dispose (TSDFs) of hazardous waste, the EPA has included arsenic on a list of hazardous constituents to be regulated through permissible concentration limits. Owners and operators of TSDFs must not allow the ground-water concentration of a hazardous constituent to exceed the background level for that constituent. The concentration of arsenic in groundwater within the boundaries of a facility must not exceed 0.05 mg/L, as long as the background concentration is below this value (EPA 1997b).

The EPA has a current maximum contaminant level (MCL) of 0.05 mg/L for arsenic in drinking water (EPA 1995e), and has recently proposed reducing the MCL to 0.005 mg/L (EPA 2000b). The World Health Organization (WHO) has established a provisional guideline value of 0.01 mg/L for arsenic in drinking water (WHO 1996).

The Occupational Safety and Health Administration (OSHA) sets permissible exposure limits (PELs) to protect workers against adverse health effects resulting from exposure to hazardous substances. The PELs determined for hazardous substances are enforceable, regulatory limits on allowable indoor air concentrations. OSHA requires employers of workers who are occupationally exposed to these hazardous substances to institute engineering controls and work practices to reduce and maintain employee exposure to at or below the PEL. An employer must ensure that no employee's exposure to inorganic arsenic is greater than 10 $\mu g/m^3$ when averaged over any 8-hour work shift (OSHA 1996b). OSHA also specifies conditions under which employees must be provided with respirators that reduce their exposure to arsenic

and arsenicals (e.g., arsenic trichloride and arsenic phosphide) to below the PEL. The concentrations of inorganic arsenic or conditions of use, and the required respirator type are given in 29 CFR 1910.1018. The requirements applicable to exposures to inorganic arsenic during construction work and for shipyard personnel are identical to those given above (OSHA 1996a, 1996c). However, for exposures to organic arsenic compounds, employers must meet the requirements that OSHA provides for occupational health and environmental controls. These requirements indicate that the exposure of employees to organic arsenic compounds in gases, vapors, fumes, dust, and mist through inhalation, ingestion, skin absorption, or contact should not exceed the "Threshold Limit Values of Airborne Contaminants for 1970" as established by the ACGIH. The ACGIH limits exposure to organic arsenic compounds to 0.5 mg/m^3 as provided in its list of "Threshold Limit Values of Airborne Contaminants for Construction" (OSHA 1997). For biological monitoring of exposures occurring in the workplace, the ACGIH provides a biological exposure index (BEI) of 50 µg/g creatinine. The BEI for a substance applies to 8-hour exposures, for 5 days/week (ACGIH 1998). The National Institute for Occupational Safety and Health (NIOSH) has established a recommended exposure level of 0.002 mg/m^3 (ceiling; 15 minutes) (NIOSH 1997).

Table 7-1. Regulations and Guidelines Applicable to Arsenic

Agency	Description	Information	References
INTERNATIONAL Guidelines:			
IARC	Carcinogenic classification (Arsenic and arsenic compounds)	Group 1[a]	IARC 1987
WHO	Provisional Guideline Value for Drinking Water	0.01 mg/L	WHO 1996
NATIONAL Regulations and Guidelines:			
a. Air			
ACGIH	TLV-TWA Arsenic, elemental and inorganic compounds	0.01 mg/m^3	ACGIH 1999
NIOSH	Recommended exposure limit Arsenic, inorganic compounds	0.002 mg/m^3	NIOSH 1999
OSHA	8-Hour Time weighted average Arsenic, organic compounds	0.5 mg/m^3	29 CFR 1910.1000 OSHA 1999a
	8-Hour Time weighted average permissible exposure limit Arsenic, inorganic compounds	10 µg/m^3	29 CFR 1910.1018 OSHA 1999b
	8-Hour Time weighted average for construction workers Arsenic, organic compounds	0.5 mg/m^3	29 CFR 1926.55 OSHA 1999d
	8-Hour Time weighted average for shipyard workers Arsenic, organic compounds	0.5 mg/m^3	29 CFR 1915.1000 OSHA 1999c
USC	List of hazardous air pollutants—Arsenic, inorganic compounds, arsine	Yes	42 USC 7412 USC 1999
b. Water			
EPA	Maximum contaminant levels for community waters systems—Arsenic	0.05 mg/L	40 CFR 141.11 EPA 1999b
	Proposed MCL for community water systems—Arsenic	0.005 mg/L	65 FR 38888 EPA 2000b
	Water Quality Criteria		EPA 1999e
	Freshwater [b]:	150 µg/L	
	Saltwater [b]:	36 µg/L	

Table 7-1. Regulations and Guidelines Applicable to Arsenic *(continued)*

Agency	Description	Information	References
NATIONAL *(contd)*			
b. Water *(contd)*			
EPA *(contd)*			
	Human health consumption of:		EPA 1999e
	water and organism[c]	0.018 µg/L	
	organism only[c]	0.14 µg/L	
FDA	Bottled water limit for arsenic	0.05 mg/L	21 CFR 165.110 FDA 1999a
c. Food			
FDA	Indirect food additive—used in animal feed as animal drugs (percent by weight of feed)		21 CFR 510.515 FDA 1999b
	Arsanilic acid	0.005<x<0.01%	
	Sodium arsanilate	0.005<x<0.01%	
	3-Nitro-4-phenylhydroxy-arsonic acid	0.0025<x<0.005%	
d. Other			
ACGIH	Arsenic, elemental and inorganic		ACGIH 1999
	Cancer classification		
	Biological Exposure Indices	A1[d]	
	Inorganic arsenic metabolites in urine	50 µg/g creatinine	
	Inorganic arsenic plus methylated metabolites in urine[e]	30 µg As/L	
EPA	Arsenic and inorganic compounds		IRIS 1999
	Carcinogenic classification	Group A[f]	
	RfD (oral)	$3x10^{-4}$ mg/kg-day	
	Oral slope factor	1.5 (mg/kg)/day	
	Drinking water unit risk	$5x10^{-5}$ µg/L	
	Inhalation unit risk	$4.3x10^{-3}$ µg/m^3	
	Reportable quantities of hazardous substances		40 CFR 302.4 EPA 1999c
	Arsenic—regarded as a CERCLA hazardous substance under 307(a) and 112 of the Clean Water Act	1 pound	40 CFR 302.4 EPA 1999c
	Arsenic acid—regarded as a CERCLA hazardous substance under section 311(b)(4) of the Clean Water Act	1 pound	40 CFR 302.4 EPA 1999c

Table 7-1. Regulations and Guidelines Applicable to Arsenic *(continued)*

Agency	Description	Information	References
NATIONAL *(contd)* d. Other *(contd)* EPA *(contd)*			
	Sodium arsenite—regarded as a CERCLA hazardous substance under section 311(b)(4) of the Clean Water Act	1 pound	40 CFR 302.4 EPA 1999c
	Arsenic pentoxide—regarded as a CERCLA hazardous substance under section 311(b)(4) of the Clean Water Act; and by RCRA section 3001	1 pound	40 CFR 302.4 EPA 1999c
	Arsenic trioxide—regarded as a CERCLA hazardous substance under section 311(b)(4) of the Clean Water Act	1 pound	40 CFR 302.4 EPA 1999c
	Calcium arsenate—regarded as a CERCLA hazardous substance under section 311(b)(4) of the Clean Water Act; and by RCRA section 3001	1 pound	40 CFR 302.4 EPA 1999c
	Listed as a CERCLA hazardous substance—dimethylarsinic acid	Yes	40 CFR 302.4 EPA 1999c
	Identification and Listing of Hazardous Waste—arsenic, arsenic acid, arsenic pentoxide, arsenic trioxide	Yes	40 CFR 261.33 EPA 1999d
	Toxic Chemical Release Reporting—effective date for arsenic	1/1/87	40 CFR 372.65 EPA 1999a
	Designated hazardous substance in accordance with section 311(b)(2)(a) of the Act—arsenic pentoxide, arsenic trioxide, calcium arsenate, and sodium arsenite	Yes	40 CFR 116.4 EPA 1998h
	Toxic pollutant designated pursuant to section 307(a)(1) of the Act	Yes	40 CFR 401.15 EPA 1998i

Table 7-1. Regulations and Guidelines Applicable to Arsenic *(continued)*

Agency	Description	Information	References
NATIONAL *(contd)* d. Other *(contd)* EPA *(contd)*			
	Statutory Designation as a Hazardous Substance	Yes	Title III Clean Water Act U.S. Congress 1977
	Pesticides severely restricted in the United States	Yes	EPA 1998a
STATE Regulations and Guidelines:			
a. Air			
Arizona	Acceptable concentrations— Arsenic and compounds 1-Hour 24-Hour. Annual Arsenic pentoxide and trioxide 24–Hour Annual	 $3.2x10^{-1}$ µg/m^3 $8.4x10^{-2}$ µg/m^3 $2.3x10^{-4}$ µg/m^3 $5.0x10^{-4}$ µg/m^3 $2.0x10^{-4}$ µg/m^3	NATICH 1992
Connecticut	Acceptable concentrations— 8-hour for arsenic and compounds	 $5.0x10^{-2}$ µg/m^3	NATICH 1992
Florida	Acceptable concentrations— Arsenic and compounds 8-Hour - Fort Lauderdale 8-Hour - Pinella 24-Hour - Pinella Annual - Pinella	 $2.0x10^{-3}$ mg/m^3 2.0 µg/m^3 $4.8x10^{-1}$ µg/m^3 $2.3x10^{-4}$ µg/m^3	NATICH 1992
Idaho	Acceptable ambient concentration for a carcinogen	$2.3x10^{-4}$ µg/m^3	ID Dept Health Welfare 1999b
Kansas	Acceptable concentrations— Arsenic and compounds Annual	 $2.3x10^{-4}$ µg/m^3	NATICH 1992
	Concentration limits for hazardous air emissions	0.005 tons/year	KS Dept. Health Environ 1998b
Louisiana	Acceptable concentrations— Arsenic and compounds Annual	 $2.0x10^{-2}$ µg/m^3	NATICH 1992
Michigan	Acceptable concentrations— Arsenic and compounds Annual	 $2.3x10^{-4}$ µg/m^3	NATICH 1992

Table 7-1. Regulations and Guidelines Applicable to Arsenic *(continued)*

Agency	Description	Information	References
STATE *(contd)*			
a. Air *(contd)*			
Montana	Acceptable concentrations— Arsenic and compounds		NATICH 1992
	Annual	$7.0x10^{-2}$ µg/m^3	
	24-Hour	$3.9x10^{-1}$/µg/m^3	
Nevada	Acceptable concentrations— Arsenic and compounds		NATICH 1992
	Annual	$5.0x10^{-3}$ mg/m^3	
New York	Acceptable concentrations— Arsenic and compounds		NATICH 1992
	Annual	$6.7x10^{-1}$ µg/m^3	
North Carolina	Annual Acceptable concentrations— Arsenic and compounds, arsenic acid and arsenic pentoxide, trichloride, trioxide, trisulfide	$2.3x10^{-7}$ mg/m^3	NATICH 1992
North Dakota	Acceptable concentrations— Arsenic and compounds		NATICH 1992
	8–Hour	$2.0x10^{-3}$ mg/m^3	
Oklahoma	Acceptable concentrations— Arsenic and compounds		NATICH 1992
	24–Hour	$2.0x10^{-2}$ µg/m^3	
Pennsylvania	Acceptable concentrations— Arsenic and compounds		NATICH 1992
	Annual	$2.4x10^{-2}$ µg/m^3	
Rhode Island	Acceptable concentrations— Arsenic and compounds		RI Dept Environ Management 1992
	Annual	0.002 µg/m^3	
South Carolina	24-hour Acceptable concentrations—Arsenic and compounds, and arsenic pentoxide	1.0 µg/m^3	NATICH 1992
Texas	Acceptable concentrations— Arsenic and compounds		NATICH 1992
	30–minute	5.0 µg/m^3	
	Annual	$5.0x10^{-1}$ µg/m^3	
Vermont	Acceptable concentrations— Arsenic and compounds		NATICH 1992
	Annual	$2.3x10^{-4}$ µg/m^3	

Table 7-1. Regulations and Guidelines Applicable to Arsenic *(continued)*

Agency	Description	Information	References
STATE *(contd)*			
a. Air *(contd)*			
Virginia	Acceptable concentrations— Arsenic and compounds 24–Hour Arsenic trisulfide 24-Hour	 3.3 µg/m^3 2.0 µg/m^3	NATICH 1992
Washington	Acceptable concentrations— Arsenic and compounds Annual	 2.3x10^{-4} µg/m^3	NATICH 1992
Wisconsin	Hazardous air contaminants without acceptable ambient concentration requiring lowest achievable emission rate	25 pounds/yr[2]	WI Dept Natural Resources 1997
b. Water			
Alabama	Drinking water quality standards and guidelines	50 µg/L	FSTRAC 1995
	Aquatic life criteria: Freshwater acute Freshwater chronic Marine acute Marine chronic Human health criteria for the consumption of: water and organism[g] organism only[g]	 360 µg/L 190 µg/L 69 µg/L 36 µg/L 1.64x10^{-4} mg/L 3.0x10^{-4} mg/L	AL Dept Environ Management 1998
Alaska	Maximum contaminant level	0.05 mg/L	AK Dept Environ Conserv 1999
Arizona	Water guideline and standard	50 µg/L	FSTRAC 1995
	HBGLs for ingestion of contaminants in drinking water Oral HBGL MCL	 0.02 µg/L 50 µg/L	AR Dept Health Services 1999
Colorado	Aquatic life based criteria for surface waters: Acute Chronic Human health based for drinking water	 360 µg/L 150 µg/L 50 µg/L	CO Dept Public Health Environ 1999

Table 7-1. Regulations and Guidelines Applicable to Arsenic *(continued)*

Agency	Description	Information	References
STATE *(contd)*			
b. Water *(contd)*			
Hawaii	Health guidelines applicable to all water:		HI Dept Health 1999a
	Freshwater		
	acute	360 µg/L	
	chronic	190 µg/L	
	Saltwater		
	acute	69 µg/L	
	chronic	36 µg/L	
	Fish consumption	NS[h]	
	MCL applicable to all public water systems	0.05 mg/L	HI Dept Health 1999b
Idaho	Ground water quality standards	0.05 mg/L	ID Dept Health Welfare 1999a
Illinois	Aquatic based water quality standards:		IL Environ Protec Agency 1999
	acute	360 µg/L	
	chronic	190 µg/L	
Kansas	Surface water quality standards for aquatic life:		KS Dept Health Environ 1998a
	Arsenic		
	acute	Not given	
	chronic	50 mg/L	
	Arsenic(III)		
	acute	379 mg/L	
	chronic	50 mg/L	
	Arsenic(V)		
	acute	850 mg/L	
	chronic	48 mg/L	
Maine	Standard	30 µg/L	FSTRAC 1990
Massachusetts	Standard	50 µg/L	FSTRAC 1990
Minnesota	Guideline	0.2 µg/L	FSTRAC 1995
New Jersey	Groundwater quality arsenic, total	0.02 µg/L	NJ Dept Environ Protec 1993
Oklahoma	Criteria for surface water designated as public and private water supplies	0.10 mg/L	OK Dept Environ Quality 1997
	Aquatic life criteria		OK Dept Environ Quality 1997
	acute	360 µg/L	
	chronic	190 µg/L	
Rhode Island	Standard	50 µg/L	FSTRAC 1990

Table 7-1. Regulations and Guidelines Applicable to Arsenic *(continued)*

Agency	Description	Information	References
STATE *(contd)*			
b. Water *(contd)*			
South Dakota	Maximum contaminant levels—apply to community and non-transient and non-community water systems	0.05 mg/L	SD Dept Environ Natural Resources 1998
Vermont		50 µg/L	FSTRAC 1995
c. Other			
Louisiana	Devil's Swamp and Bayou Baton rouge—wildlife advisory applying to the general population	All fish species	EPA 1997e
Oregon	Willamette river—1,000 feet around the McCormack and Baxter wood treatment site—enforcing a commercial fishing ban	Shellfish-crayfish	EPA 1997e
Washington	Ostrich Bay—wildlife advisory recommending no consumption by the general population	Shellfish-crab, Shellfish, and all bottomfish	EPA 1997e

[a]Group 1=Carcinogenic to humans; classification applies to the group of compounds as a whole but not necessarily to each individual compound in the group.
[b]Freshwater and saltwater criteria for metals are expressed in terms of the dissolved metal in the water column
[c]This criteria applies to inorganic arsenic only, it is currently being reassessed by the Environmental Protection Agency and it is based on carcinogenicity of 10^{-6} risk.
[d]Confirmed human carcinogen
[e]Notice of intended change
[f]Confirmed human carcinogen
[g]The following equations were used to calculate the values as given in the Alabama State laws:

Consumption of water and organism:

Concentration (mg/L) = (HBW x RL)/(CPF x [(FCR x BCF) + WCR])

Consumption of organism only:

Concentration (mg/L) = (HBW x RL)/(CPF x FCR x BCF)

HBW = human body weight, set at 70 kg
RL = risk level, set at $1x10^{-5}$
CPF = cancer potency factor, 1.75 (kg-day)/mg
FCR = fish consumption rate, set at 0.030 kg/day
BCF = bioconcentration factor, 44 L/kg for toluene
WCR = water consumption rate, set at 2 L/day

[h]NS: no standard has been developed as yet.

ACGIH = American Conference of Governmental Industrial Hygienists; CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; CFR = Code of Federal Regulations; EPA = Environmental Protection Agency; FDA = Food and Drug Administration; FSTRAC = Federal State Toxicology and Regulatory Alliance committee; IARC = International Agency for Research on Cancer; MCL = maximum contaminants level; NATIC = National Air Toxics Information Clearinghouse; NIOSH = National Institute of Occupational Safety and Health; OSHA = Occupational Safety and Health Administration; RfD = Oral Reference Dose; TLV = Threshold Limit Value; TWA = time-weighted average; USC = United States Code; WHO = World Health Organization